Remarks/Arguments

The foregoing amendments to the claims are of formal nature, and do not add new matter. Claims 119-138 are pending in this application and are rejected/objected to on various grounds. Claims 139-142 have been added, support for which is found in canceled claim 132 and in the instant specification at page 285, line 11 onwards. Entry of these claims is respectfully requested. Claims 127-128, 132-134 have been canceled without prejudice or disclaimer to claim its subject matter in subsequent continuation or divisional applications. Accordingly, Claims 119-126, 129-131 and 135-142 are now pending in this application.

Claims 124-131 have been indicated as allowable. Claims 119-128 and 137 have been amended for clarity to particularly claim what the Applicants consider is their invention and with the recitation "wherein said nucleic acid is amplified in lung or colon tumors," support for which is found in Example 170 of the instant specification. The rejections to the presently pending claims are respectfully traversed.

Priority

Applicants submit that they rely on the gene amplification assay for patentable utility which was first disclosed in U.S. Provisional Application 60/141,037, filed June 23, 1999, priority to which has been claimed in this application. Based on the disclosure of SEQ ID NO: 29, Figure 20 (that encodes PRO943) in Application 60/141,037, Applicants believe that the application provides adequate support and that meets the requirements of 35 USC § 101 and 112, first paragraph. Hence, Applicants should be entitled to at least an effective filing date of **June 23, 1999.**

Specification

The title of the invention has been amended to indicate, more clearly, the claimed invention.

The disclosure was objected to by the Examiner as containing "embedded hyperlink and/or other form of browser-executable code." The foregoing amendment to the specification which deleted all embedded hyperlinks, is believed to overcome the present objections.

Accordingly, Applicants believe that all objections to the specification has been overcome.

Information Disclosure Statement

Applicants submit an IDS separately enlisting references recited in the Blast report filed 3/25/2002 in order to be compliant with 37 C.F.R. § 1.98(a)(1). Consideration of this Information Disclosure Statement is respectfully requested.

Claim Rejections – 35 U.S.C. §112, First Paragraph- Enablement

Claims 119-123, 132-138 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while enabling for a nucleic acid encoding a full length PRO943 protein of SEQ ID NO: 119, or a nucleic acid of SEQ ID NO: 118, does not reasonably provide enablement for a nucleic acid at least 80-99% identical to SEQ ID NO: 118, or a nucleic acid at least 80-99% identical to a nucleic acid encoding SEQ ID NO: 119. For the reasons outlined below, Applicants respectfully traverse.

The cancellation of claims 127-128 and 132-134 without prejudice or disclaimer, renders this rejection moot to these claims. Further, without acquiescing to the propriety of this rejection, Applicants have amended Claims 119-123 to recite a functional recitation: "wherein said nucleic acid is amplified in lung or colon tumors." Applicants have also included the high stringency hybridization conditions under which the probes of claims 139-145 are useful for the diagnosis of lung or colon cancer. Based on the detailed description of the cloning and expression of nucleic acid variants of PRO943 in the specification, the description of the gene amplification assay and description of testing the ability of test variant polypeptides in the assay, the actual reduction to practice of sequence SEQ ID NO: 119 and the functional recitation in the instant claims, Applicants submit that one of skilled in the art would know how to make and use the claimed variants, as a lung or colon tumor marker.

Thus, Applicants believe that these rejections under 35 U.S.C. §112, first paragraph, should be withdrawn.

Claim Rejections – 35 U.S.C. §112, First Paragraph - Written Description

Claims 119-123 and 132-138 are rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement. The Examiner contends that "the claims contain subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention." Applicants respectfully traverse this rejection to the pending claims.

The Legal standard for Written Description

The well- established test for sufficiency of support under the written description requirement of 35 U.S.C. §112, first paragraph, is whether the disclosure "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *In re* Kaslow, 707 F.2d 1366, 1375, 212 USPQ 1089, 1096 (Fed. Cir. 1983); see also Vas-Cath, Inc. v. Mahurkar, 935 F. 2d at 1563, 19 USPQ2d at 1116 (Fed. cir. 1991). The adequacy of written description support is a factual issue and is to be determined on a case-by-case basis. see *e.g.*, Vas-Cath, Inc. v. Mahurkar, 935 F. 2d at 1563, 19 USPQ2d at 1116 (Fed. cir. 1991). The factual determination in a written description analysis depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure. Union Oil v. Atlantic Richfield Co., 208 F. 3d 989, 996 (Fed. Cir. 2000).

Arguments

As noted above, whether the Applicants were in possession of the invention as of the effective filing date of an application is a factual determination, reached by the consideration of a number of factors, including the level of knowledge and skill in the art, and the teaching provided by the specification. The inventor is not required to describe every single detail of his/her invention. An Applicant's disclosure obligation varies according to the art to which the invention pertains.

The instant invention, defined by the claims, concerns nucleic acids having 80%, 85%, 90%, 95% or 99% sequence identity with the disclosed nucleic acid sequence of SEQ ID NO: 118 and further, recite the functional recitation: "wherein the nucleic acid encoding said polypeptide is amplified in lung or colon tumors." The present invention pertains to the field of recombinant DNA/protein technology. It is well established that the level of skill in this field is very high since a representative person of skill is generally a Ph.D. scientist with several years of experience. Accordingly, the teaching imparted in the specification must be evaluated through the eyes of a highly skilled artisan as of the date the invention was made. Based on the detailed description of the cloning and expression of variants of PRO943 in the specification, the description of the gene amplification assay and description of testing the ability of test variant

polypeptides in the assay, the actual reduction to practice of sequences SEQ ID NO: 118 and the functional recitation in the instant claims, Applicants submit that one of skilled in the art would know that Applicants possessed the invention as claimed in the instant claims.

Hence, Applicants submit that this rejection should be withdrawn.

Claim Rejections – 35 U.S.C. §112, First Paragraph- Enablement

Claim 137 was rejected under 35 U.S.C. §112, first paragraph, while being enabling for a host cell in culture, does not provide enablement for "*in vivo*" transfection.

Without acquiescing to the propriety of this rejection, Applicants have amended claim 137 to recite "an isolated host cell." Accordingly, this rejection should be withdrawn.

Claim Rejections – 35 U.S.C. §102(a)

1. Claims 119-122, 132-138 are rejected under 35 U.S.C. §102(a) as being anticipated by Aggarwal *et al.* (dated 2001).

2. Claims 119, 132-138 are rejected under 35 U.S.C. §102(b) as being anticipated by Wiedemann *et al.* (dated 2000).

Based on the discussions above, since the pending claims are at least entitled to a priority date of **June 23, 1999**, Applicants submit that neither Aggarwal nor Wiedemann are prior art and request that these rejections be withdrawn.

The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. **08-1641**, referencing Attorney's Docket No. **39780-2730 P1C51**.

Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: August 4, 2004

By: Daphne Reddy
Daphne Reddy
Reg. No. 53,507

HELLER EHRMAN WHITE & McAULIFFE LLP
Customer No. 35489
275 Middlefield Road
Menlo Park, California 94025
Telephone: (650) 324-7000
Facsimile: (650) 324-0638

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